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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/257,739	02/25/1999	SHALOM Z. HIRSCHMAN	4493-36	2898

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EXAMINER
BUDENS, ROBERT D

ART UNIT	PAPER NUMBER
1648	15

DATE MAILED: 05/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The Examiner acknowledges Applicant's Amendment, Paper No. 14, filed February 12, 2002. In view of Applicant's Amendment, the status of the claims is as follows: Claims 5-6 have been canceled; Claims 1-4 and 7-9 are currently pending before the Examiner.

Claims 1-4 and 7-9 remain rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons of record set forth in the last Office Action. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection. While Applicant has made a *bona fide* attempt at correcting the problems of method step numbering, the removal of any delimiter between the method step identifier (e.g., "a" or "b") makes it unclear whether the identifier is actually an identifier or part of the method step. Amendment of claims 1 and 7 to recite "a) culturing cells..." or some other form of delimiter (but not a period) would obviate this rejection. Further, while Applicant has discussed the means of comparing RT-PCR results in Applicant's Response, similar language is not found in the claims. Applicant has amended the claims to indicate that the RT-PCR results are compared to each other, but the claimed method steps do not indicate how that comparison to each other is interpreted to determine down-regulation of gene expression.

Claims 1-4 and 7-9 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons of record set forth in the last Office Action. Applicant's arguments have been fully

considered but are not deemed persuasive to overcome the rejection. Applicant argues that the specification provides sufficient two specific methods for preparing Product R and that one skilled in the art could therefore determine what would constitute "a predetermined amount" (see Paper No. 14, paragraph bridging pages 6-7). Applicant further argues that the claims have been amended to specifically recite how the RT-PCR amounts are compared. This is not persuasive.

With respect to the comparison of the RT-PCR amounts, these arguments are essentially identical to the arguments made in the response to the rejection under 35 U.S.C. § 112, second paragraph, and have been addressed above.

With respect to the preparation of Product R, Applicant has again argued limitations not found in the claims. There is no clear indication how the claim language "a predetermined amount" would necessarily and specifically correlate with the examples set forth in the specification. Applicant should consider setting forth in the claims, the specific method steps for producing Product R, including specific amounts of reagents necessary to produce Product R. In the absence of convincing objective evidence to the contrary, the rejection is deemed proper and is maintained for the reasons of record.

The claimed invention appears free of the art for the following reasons. The closest relevant art are Hirschman, U.S. Patent No. 5,807,839 (A), Hirschman, U.S. Patent No. 5,807,840 (B), Bregman, U.S. Patent No. 5,902,786 (C), and most notably, Hirschman et al., *J. Investigative Medicine* 44(6):347-351, August 1996 (R).

Each of Hirschman (A), Hirschman (B) and Bregman (C) disclose Product R (Reticulose) which appears to be identical to the Product R of the instant application. Further, each of the references

teach different clinical uses for Product R. However, none of the references teach the use of Product R in methods for determining down-regulation of a chemokine receptor.

Hirschman et al. (R), the most relevant prior art, discloses methods for studying the mechanisms of action of Product R (Reticulose) using H9 T lymphoma cells and HIV infection (see page 348, "Materials and Methods"). These methods appear analogous to the methods of the claimed invention except that Hirschman et al. does not specifically study the down-regulation of a chemokine receptor which is a coreceptor for HIV. The Examiner notes that in the previous May and June of 1996, just prior to publication of Hirschman et al. (R), several laboratories essentially simultaneously identified CXCR4 and CCR5, chemokine receptors on the surface of T cells, as the putative coreceptors for HIV infection. Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use the methods of Hirschman et al. (R) to study the effects of Product R on chemokine receptor expression. However, it is the Examiner's opinion that, while one of ordinary skill in the art would have been motivated to undertake studies to determine if Product R had any effect on chemokine receptor expression based on the knowledge that CXCR4 and CCR5 were known coreceptors for HIV, there exists no reasonable expectation of success in such an undertaking. It is the Examiner's opinion that the prior art did not recognize any relationship between Product R and chemokine receptor down-regulation. Therefore, while one of ordinary skill in the art would have been motivated, such an attempt would constitute an "obvious to try" situation with no reasonable expectation of success. On this basis, the Examiner holds Applicant's claimed invention free of the prior art.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Robert D. Budens at (703) 308-2960. The Examiner can normally be reached Monday-Thursday from 6:30 AM-4:00 PM, (EST). The Examiner can also be reached on alternate Fridays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, James Housel, can be reached at (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at (703) 308-0196.

Robert D. Budens
Primary Examiner
Art Unit 1648

rdb
May 6, 2002